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**8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K020313.

**Submitter:**

ACON Laboratories, Inc.  
4108 Sorrento Valley Boulevard  
San Diego, California 92121

Tel.: 858-535-2030  
Fax: 858-535-2038

**Date:** January 28, 2002

**Contact Person:** Edward Tung, Ph.D.

**Product Names:**

ACON One Step Multi-Drug Multi-Line Screen Test Card

ACON One Step Multi-Drug Multi-Line Screen Test Device

**Common Name:**

Immunochromatographic test for the simultaneously qualitative detection of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine in urine.

**Device Classification:**

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine in urine specimens. These tests are used to provide a preliminary analytical result only. Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine test systems have been classified as Class II devices with moderate complexity.

**Classification Name:**

Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine test system

**Intended Use:**

The ACON<sup>®</sup> One Step Multi-Drug Multi-Line Screen Test Card and Test Device are rapid chromatographic immunoassays for the qualitative and simultaneous detection of two to six drugs in a variety of combinations in human urine samples. The designated cut-off concentrations for these drugs are as follows: Amphetamine at 1,000 ng/ml, Cocaine at 300 ng/ml, Methamphetamine at 1,000 ng/ml, Opiates at 2,000 ng/ml, Marijuana at 50 ng/ml and Phencyclidine at 25 ng/ml. They are intended for healthcare professionals including professionals at the point of care sites.

**Description:**

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine in urine samples. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibodies to selectively detect elevated levels of Amphetamine, Methamphetamine, Cocaine, Opiates, THC and PCP in urine at the cut-off concentrations of 1,000 ng/ml (AMP), 1,000 ng/ml (mAMP), 300 ng/mL (COC), 2,000 ng/ml (OPI), 50 ng/ml (THC) and 25 ng/ml (PCP). These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine at the concentrations below the designated cut-off levels will generate a colored-line in the designated test region for the drug. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**Predicate Devices:**

ACON<sup>™</sup> of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine Single Drug Test strips were used as the predicate devices for the ACON<sup>®</sup> One Step Multi-Drug Multi-Line Screen Test Card and Test Device to compare their performance with clinical urine specimens.

510(k) Number for these predicate devices are:

ACON AMP One Step Amphetamine Test Strip	K011673
ACON mAMP One Step Methamphetamine Test Strip	K011672
ACON COC One Step Cocaine Test Strip	K010841
ACON OPI One Step Opiates Test Strip	K011353
ACON THC One Step Marijuana Test Strip	K003557
ACON PCP One Step Phencyclidine Test Strip	K011730

**Comparison to a Predicate Device:**

A comparison of the features of the ACON™ One Step Multi-Drug Multi-Line Screen Test Card and Test Device versus the ACON™ Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine Single Tests is shown below:

- Both tests are assays intended for the qualitative detection of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine with a visual, qualitative end result, while ACON Multi-Drug Multi-Line Test detects 2 to 6 of the above drugs simultaneously.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have the same cut-off for each drug test.

**Safety and Effectiveness Data:****Accuracy**

A clinical evaluation was conducted using clinical urine specimens. This evaluation compared the test results between ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device versus previously FDA-cleared Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine Single tests; as well as against data obtained from the customary GC/MS analysis. Over 1,000 clinical specimens were employed including approximately 10% of the samples with drug concentrations in the -25% to +25% cut-off range. The comparisons of data obtained from this study yielded the following results:

**ACON One Step Multi-Drug Multi-Line Screen Test Card**

**vs.**

**Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine Single Tests:**

<b>ACON Test Card</b>	<b>Positive Agreement</b>	<b>Negative Agreement</b>	<b>Overall Agreement</b>
<b>AMP</b>	129/129=>99% (97% - 99%)*	172/172=>99% (98% - 99%)*	301/301=> 99% (98% - 99%)*
<b>COC</b>	112/112 = >99% (97% - 99%)*	186/187 = 99% (97% - 99%)*	298/299 = 99% (98% - 99%)*
<b>mAMP</b>	121/122 = 99% (96% - 99%)*	174/174 = >99% (98% - 99%)*	295 / 296 = 99% (98% - 99%)
<b>OPI</b>	131/133 = 98% (95% - 99%)*	164/164 = >99% (98% - 99%)	295/297 = >99% (97% - 99%)
<b>THC</b>	124/124 = >99% (97% - 99%)*	175/176 = 99% (97% - 99%)*	299 / 300 = 99% (98% - 99%)*
<b>PCP</b>	71/72 = 99% (93% - 99%)*	160/160 = >99% (98% - 99%)*	231/232 = 99% (97% - 99%)*

\* 95% Confidence Interval

**ACON One Step Multi-Drug Multi-Line Screen Test Device**

**vs.**

**Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine Single Test:**

<b>ACON Test Device</b>	<b>Positive Agreement</b>	<b>Negative Agreement</b>	<b>Overall Agreement</b>
<b>AMP</b>	129/129=>99% (97% - 99%)*	172/172=>99% (98% - 99%)	301/301=> 99% (98% - 99%)*
<b>COC</b>	112/112 = >99% (97% - 99%)*	186/187 = 99% (97% - 99%)*	298/299 = 99% (98% - 99%)*
<b>mAMP</b>	121/121 = >99% (97% - 99%)*	175/175 = >99% (98% - 99%)*	296 / 296 = >99% (98% - 99%)*
<b>OPI</b>	132/133 = 99% (96% - 99%)*	164/164 = >99% (98% - 99%)	296/297 = 99% (98% - 99%)*
<b>THC</b>	124/124 = >99% (97% - 99%)*	175/176 = 99% (98% - 99%)*	299 / 300 = 99% (98% - 99%)*
<b>PCP</b>	71/72 = 99% (95% - 99%)*	160/160 = >99% (98% - 99%)*	231/232 = 99% (97% - 99%)*

\* 95% Confidence Interval

Clinical study results of ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are compared to GC/MS analysis data:

The GC/MS cut-off levels for each of the six drugs tested are as following:

Amphetamine	1,000 ng/ml
Cocaine	300 ng/ml
Methamphetamine	1,000 ng/ml
Opiate	2,000 ng/ml
Marijuana	50 ng/ml
Phencyclidine	25 ng/ml

Samples with drug concentration above the cut-off level were considered presumptive positive and concentrations below the cut-off are considered negative.

**ACON One Step Multi-Drug Multi-Line Screen Test Card  
vs.  
GC/MS Analysis**

ACON Test Card	Positive Agreement	Negative Agreement	Overall Agreement
<b>AMP</b>	129/136=95% (90% - 98%)*	164/165=99% (97% - 99%)*	293/301= 97% (95% - 99%)*
<b>COC</b>	112/118 = 95% (89% - 98%)*	180/181 = 99% (97% - 99%)*	292/299 = 98% (95% - 99%)*
<b>mAMP</b>	121/134 = 90% (84% - 94%)*	162/162 = >99% (98% - 100%)*	283 / 296 = 96% (93% - 98%)*
<b>OPI</b>	130/131 = 99% (96% - 99%)*	164/166 = 99% (96% - 99%)*	294/297 = 99% (97% - 99%)*
<b>THC</b>	116/122 = 95% (90% - 98%)*	169/178 = 95% (91% - 98%)*	285 / 300 = 95% (92% - 97%)
<b>PCP</b>	70/78 = 90% (81% - 95%)*	153/154 = 99% (96% - 99%)*	223/232 = 96% (93% - 98%)*

\* 95% Confidence Interval

**ACON One Step Multi-Drug Multi-Line Screen Test Device**  
**vs.**  
**GC/MS Analysis**

ACON Test Device	Positive Agreement	Negative Agreement	Overall Agreement
<b>AMP</b>	128/136=94% (89% - 97%)*	164/165=99% (97% - 99%)*	292/301= 97% (94% - 99%)*
<b>COC</b>	112/118 = 95% (89% - 98%)*	180/181 = 99% (97% - 99%)*	292/299 = 98% (95% - 99%)*
<b>mAMP</b>	120/134 = 90% (83% - 94%)*	162/162 = >99% (98% - 100%)	282 / 296 = 95% (92% - 97%)*
<b>OPI</b>	130/131 = 99% (96% - 100%)	164/166 = 99% (96% - 99%)*	294/297 = 99% (97% - 99%)*
<b>THC</b>	116/122 = 95% (90% - 98%)*	170/178 = 96% (91% - 98%)*	286 / 300 = 95% (92% - 97%)*
<b>PCP</b>	70/78 = 90% (81% - 95%)*	152/154 = 99% (96% - 99%)*	222/232 = 96% (92% - 98%)*

\* 95% Confidence Interval

**Conclusion:**

Clinical study results demonstrate the substantial equivalency between the ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device and the Amphetamine, Methamphetamine, Cocaine, Opiates, THC and PCP single tests, which has already being cleared by FDA and marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Amphetamine, Cocaine, Methamphetamine, Opiates, Marijuana, and Phencyclidine at the following cut-off concentrations: Amphetamine 1,000 ng/ml, Cocaine 300 ng/ml, Methamphetamine 1,000 ng/ml, Opiates 2,000 ng/ml, THC 50 ng/ml and PCP 25 ng/ml. The physician's office laboratory POL study demonstrated that these tests are also suitable for use by professional at point-of-care site.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 08 2002

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Edward Tung, Ph.D.  
Director of Regulatory Affairs  
ACON Laboratories, Inc.  
4108 Sorrento Valley Blvd.  
San Diego, CA 92121

Re: k020313  
Trade/Device Names: ACON® One Step Multi-Drug Multi-Line Screen Test Card  
ACON® One Step Multi-Drug Multi-Line Screen Test Device  
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3250; 21 CFR 862.3870;  
21 CFR 862.3650; 21 CFR 862.3610  
Regulation Name: Amphetamine test system; Cocaine and cocaine metabolite test  
System; Cannabinoid test system; Opiate test system;  
Methamphetamine test system  
Regulatory Class: Class II; Class II; Class II; Class II, Class II  
Product Code: DKZ; DIO; LDJ; DJG; LCM; LAF  
Dated: April 8, 2002  
Received: April 12, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K020313

Device Name: ACON® One Step Multi-Drug Multi-Line Screen Test Card  
ACON® One Step Multi-Drug Multi-Line Screen Test Device

Indications for Use:

The ACON® One Step Multi-Drug Multi-Line Screen Test Card and Test Device are rapid chromatographic immunoassays for the qualitative and simultaneous detection of two to six drugs in a variety of combinations in human urine. The designated cut-off concentrations for these drugs are as follows: Amphetamine at 1,000 ng/ml, Cocaine at 300 ng/ml, Methamphetamine at 1,000 ng/ml, Opiates at 2,000 ng/ml, Marijuana at 50 ng/ml and Phencyclidine at 25 ng/ml. They are intended for healthcare professionals including professionals at the point of care sites.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical  
510(k) Number K020313

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

Or Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)